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10/564,368

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Atsushi Yamagishi

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EXAMINER

SUTTON, DARRYL C

ART UNIT

PAPER NUMBER

1612

NOTIFICATION DATE

DELIVERY MODE

07/23/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/564,368 | Applicant(s) YAMAGISHI ET AL. | |
| | Examiner DARRYL C. SUTTON | Art Unit 1612 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3 and 5-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,3 and 5-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/30/2009 has been entered. Claim 4 has been canceled. New claims 22-29 have been added.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

(1) Claims 2, 3, 5-7, 9, 12, 13 and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winston et al. (WO 1998/13012) in view of Ubsen et al. (US 5,605,675) and further in view of Tomlinson et al. (4,048,300).

Winston teaches an improved two part product for remineralizing or mineralizing teeth with a separating means for separating the components (Abstract), and a two part packaged product (page 42, lines 4-20). Winston also teaches an embodiment of the

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product which contains sodium fluoride and monoammonium phosphate in one component with an aqueous pH of 5.38 and calcium malonate in the other component with an aqueous pH of 6.83 (page 61, Example G, page 27, lines 23-28, page 59, lines 14-20, page 64, lines 10-14). Water soluble inorganic phosphate salts for use in the invention include alkali and ammonium salts of orthophosphoric acid (page 28, lines 15-22). Non-limiting examples of oral products include, tooth pastes, gels, mouthwashes, mouthrinses and the like (page 15, lines 9-14). The anionic part contains at least one water soluble fluoride salt and the cationic component contains at least one water-soluble calcium salt (page 20, lines 23-29, lines 54-56), i.e. the composition can contain more than one fluoride source. Water soluble fluoride salts, including alkali metal monofluorophosphates can be used in the invention; if monofluorophosphate salts are used as a fluoride source these salts can be present in the first phase along with the calcium cations (page 29, lines 3-17). Water-soluble calcium compounds include calcium malate and calcium malonate (page 27, lines 16-22). Typically, at least about 10 seconds is required for diffusion of the remineralizing concentration of calcium and phosphate ions (page 34, lines 10-13). The two components are mixed quickly and timely applied to prevent premature precipitation outside the dentin (page 36, lines 19-29).

Winston et al. does not teach the method of alternately applying the separate compositions; a calcium salt of a polyol phosphate; or the molar ratios or amounts of compounds as claimed in claims 6 and 26-29.

Ubsen et al. teach two phase compositions for remineralizing teeth; one phase contains a water-soluble calcium compound and the other contains a water-soluble inorganic phosphate and a fluoride compound (Abstract). Suitable water-soluble calcium compounds include calcium malate and calcium glycerophosphate (column 5, lines 10-20), i.e. calcium glycerophosphate is equivalent to calcium malate.

Ubsen et al. does not teach that the components are alternately applied.

Tomlinson et al. teach dental preparations, such as toothpastes, tooth powders, gels and mouth washes, having calcium and phosphate components (Abstract, column 10, lines 28-30, column 18, lines 40-41). The novel compounds of the invention can be used in oral preparations and provide a long-term source of components for the remineralization of dental enamel (column 6, lines 52-58). Tomlinson teaches a composition with a first component comprised of fluoride and orthophosphoric acid with a pH of about 3 to 4; and a second component comprised of comprised of a calcium salt having a pH of about 7 (column 9, lines 28-39). Tomlinson teaches a method of alternately applying the compositions to the teeth. The teeth are subjected to fluctuating pH in the presence of fluoride, orthophosphate, and calcium ions which not only serves to prevent loss of calcium and orthophosphate ions from dental enamel, but also facilitates growth and development of the apatite crystals so that some remineralization of pits and fissures in the tooth enamel occurs. Optimum incorporation of fluoride ions into the apatite crystals structure occurs as the pH range rises from about 4 to about 7 (column 8, lines 47-68, column 17, Example 12). Apatite material containing fluoride containing materials serves to provide anti-caries protection and

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remineralization (column 10, lines 39-44). When orthophosphoric acid is used, an additional source of calcium ions is required such as from calcium carbonate (column 5, lines 24-27).

Tomlinson does not teach the specific embodiment comprised of the two components of the composition; or the molar ratios or amounts of compounds as claimed in claims 2-7, 9, 12, 13 and 26-29.

At the time of the invention, it would have been obvious for one of ordinary skill in the art to modify the composition of Winston to contain calcium glycerophosphate of Ubsen et al. since it is an equivalent water-soluble calcium salt that is used in two component compositions for tooth remineralization. Further, it would have been obvious to include the monofluorophosphate salt in the component with the calcium ions, along with incorporation of an inorganic fluoride salt, i.e. sodium fluoride, in the first component since Winston et al. teaches such incorporation and that the composition is comprised of at least one fluoride salt.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the method suggested by combining Winston et al. and Ubsen et al. to the method of alternately applying the separate compositions to teeth of Tomlinson et al. motivated by the desire to facilitate the remineralization and anti-caries protection of pits and fissures in tooth enamel by simultaneously producing the optimum incorporation of fluoride ions as taught by Tomlinson et al. Further, it would negate the necessity to quickly mix and apply the composition as taught by Winston et al., thereby facilitating the dissolution and precipitation inside of the dentin of teeth.

In regards to claims 6, and 26-29, the prior art does not teach the specific concentrations or molar ratios of the compounds. However, the invention suggested by combining Winston et al., Ubsen et al. and Tomlinson et al. is comprised of from about 0.05% to 15% of a phosphate salt, from about 0.05% to 15% of a calcium salt and fluoride salt from about 0.01 to about 5%, other ingredients of the composition are optional, i.e. "may" be used, therefore, optimization of remineralization and optimization of the incorporation of fluoride in apatite crystals is obtained through routine experimentation by varying the amounts of the phosphate salt, fluoride salt, and calcium salt in the respective solvents or carriers and optionally adding and varying the amounts of other ingredients; and would result in the concentrations and molar ratios of the instant claims.

(2) Claims 14-17 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winston et al. Ubsen et al. and Tomlinson et al. as applied to claims 2, 3, 5-7, 9, 12, 13 and 26-29 above, and further in view of Grabenstetter et al. (U.S. 4,083,955).

Winston et al. is discussed above.

Winston et al. does not specifically teach the times required for application of each component.

Ubsen et al. is discussed above.

Ubsen et al. does not teach the times required for application of each component.

Tomlinson et al. is discussed above.

Tomlinson et al. does not teach the times ranges for application of each component is from 5 to 30 seconds.

Grabenstetter et al. teach two compositions comprised of a cation, i.e. calcium, and an anion, i.e. phosphate which are sequentially applied to dental enamel resulting in mineralization of dental enamel (Abstract). The sequential application consists of two steps which may be performed in any order (column 2, lines 13-20). While the length of contact is not critical, it is necessary for the length of time to be great enough to allow diffusion of the ions through the tooth's surface (column 2, lines 51-56). The components can be sequentially delivered to the surface of the tooth by means of two separate delivery vehicles, each containing one component. The ionic ingredients can be topically applied by means of tape or other adhesive material (column 5, lines 23-27). Examples of two vehicle systems are mouthwash-mouthwash, toothpaste-toothpaste, toothpaste-mouthwash; and so forth.

Grabenstetter et al. do not teach the composition of claim 9.

In regards to claims 14-17, where the general conditions of a claim are disclosed in the prior art, it is not inventive to determine the optimum or workable ranges through routine experimentation. Therefore, the remineralization of teeth can be optimized through routine experimentation by varying amount of each component applied to the teeth and the amount of time each component is applied to the teeth; and by varying the amount of repetitions of the method.

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In regards to claim 21, it would have been obvious to modify the delivery vehicle of each component since it is well known in the art that combinations of different delivery vehicles has been used to facilitate tooth remineralization.

(3) Claims 8, 10, 11 and 18-20 and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winston et al., Ubsen et al., Tomlinson et al. and Grabenstetter et al. as applied to claims 14-17 and 21 above, and further in view of Wiesel (U.S. Patent 6,287,120).

Winston et al. is discussed above.

Winston et al. do not teach a carrier selected from paper, cloth, nonwoven fabric, absorbent cotton, sponge or porous film.

Ubsen et al. is discussed above.

Ubsen et al. do not teach a carrier selected from paper, cloth, nonwoven fabric, absorbent cotton, sponge or porous film.

Tomlinson et al. is discussed above.

Tomlinson et al. do not teach a carrier selected from paper, cloth, nonwoven fabric, absorbent cotton, sponge or porous film.

Grabenstetter et al. is discussed above.

Grabenstetter et al. does not teach a carrier selected from paper, cloth, nonwoven fabric, absorbent cotton, sponge or porous film.

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Wiesel teaches an embodiment of a carrier coated with a paste, gel or solution which contains medicaments which promote the repair or remineralization of tooth enamel (Abstract, column 8, lines 28-36). Wiesel teaches that the carrier is a non-woven, porous material which is first dipped in one solution and that additional solution may be applied to the porous material while it remains on the patient's teeth (column 3, lines 65-67, column 4, lines 1-5).

Wiesel does not teach a composition comprised of two components.

At the time of the invention it would have been obvious to modify the product and method suggested by combining Winston et al., Ubsen et al., Tomlinson et al. and Grabenstetter et al. to include the carrier of Wiesel since the method of applying compositions for remineralization of teeth with a carrier was known in the art.

In regards to claim 11, it would have been obvious to impregnate the carrier with water immediately prior to application to a tooth motivated by the desire to mix either composition with water to produce either phosphate or calcium ions immediately before applying the device to teeth.

In regards to claim 20, at the time of the invention it would have been obvious to modify the product suggested by combining Winston et al., Ubsen et al., Tomlinson et al., Grabenstetter et al. and Wiesel to be comprised of a mouthwash and dentifrice since the components for remineralizing teeth can be applied in different delivery vehicles as taught by Grabenstetter et al.

In regards to claims 22-25, the prior art does not teach the specific concentrations or molar ratios of the compounds. However, the invention suggested by

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combining Winston et al., Ubsen et al., Tomlinson et al., Grabenstetter et al. and Weisel et al. is comprised of from about 0.05% to 15% of a phosphate salt, from about 0.05% to 15% of a calcium salt and fluoride salt form about 0.01 to about 5%, other ingredients of the composition are optional, i.e. "may" be used, therefore, optimization of remineralization and optimization of incorporation of fluoride in apatite crystals is obtained through routine experimentation by varying the amounts of the phosphate salt, fluoride salt, and calcium salt in the respective solvents or carriers and optionally including and varying the amounts of other ingredients and would result in the concentrations and molar ratios of the instant claims.

All claims are rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is (571)270-3286. The examiner can normally be reached on M-Th from 7:30AM to 5:00PM EST or on Fr from 7:30AM to 4:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass, can be reached at (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Darryl C Sutton/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612